Corona antigen rapid test approved for clinical study

Lifecare's partner Digital Diagnostics AG has received approval for clinical tests from the responsible ethics committee and the Federal Institute for Drugs and Medical Devices (BfArM) in Germany. This is a decisive regulatory step in the ongoing regulatory process for the Digid Cantisense™ SARS-CoV-2 test in Germany. The Digid Cantisense ™ SARS-CoV-2 antigen test for immediate virus detection is based on ground-breaking proprietary technology, hence the approval processes are thorough and time consuming.

Lifecare AS (LIFE-ME) has a 25% ownership in Digital Diagnostics AG as part of a wider technology cooperation and joint venture with the German company.

Digital Diagnostics applied to the Federal Institute for Drugs and Medical Devices (BfArM) for approval of the Digid Cantisense ™ SARS-CoV-2 test for Germany at the beginning of June 2020. The BfArM has now permitted clinical trials to be carried out. Meanwhile, the ethics committee of the State Medical Association of Rhineland-Palatinate has also given a positive endorsement.

The aim of the test series is to demonstrate a comparable reliability of the rapid test as with conventional PCR tests. With the new test, which is particularly suitable for access control and rapid tests, for example at airports, in hospitals or at large-scale events, SARS-CoV-2 viruses can be detected directly onsite in just a few minutes.

"We are very pleased with the positive results from the regulatory scrutiny in Germany. While we would wish for a speedier regulatory approval process**,** we highly appreciate the thoroughness and long hours put in at the German and US regulatory bodies. We expect that the clinical tests will confirm Digital Diagnostics claims and meet the regulatory expectations, and we expect the product will be a robust solution fighting the pandemic", says Christian Hysing-Dahl, chairman of the board of Lifecare AS.

The clinical tests of the digital biosensor and the measuring device are expected to be completed in October 2020. If the results are positive, the rapid test is expected to be approved shortly afterwards.

In the study, patients are tested simultaneously both with a standard PCR method and with the Digid Cantisense ™ SARS-CoV-2 test. For this purpose, a throat swab is taken from the patient by the medical staff. The aim of the study is to use the Digid instant test to meet the reference values of a PCR laboratory test. The study will continue until at least 30 patients with positive PCR results have been tested. This also corresponds to the requirements of the EU Commission for in-vitro measurement methods for the detection of SARS-CoV-2.

In contrast to the PCR method, the new antigen test delivers clear electronic "YES" or "NO" information within a few minutes and saves the detour to a laboratory and valuable time during diagnosis.

In addition, the Digid Cantisense™ SARS-CoV-2 test directly detects the presence of the virus, while other available rapid tests mainly detect antibodies. However, patients only develop these antibodies if they have been infected for several days and have already been contagious. For this reason, rapid antibody tests are only of limited use in containing the spread of the pandemic.

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